

## REMARKS

In response to the objection to the abstract, an amended Abstract has been provided which adds to the original Abstract a recitation of the elected species, which is representative of the class of novel compounds. However, it is stated for the record that it is believed that the original Abstract does disclose the novelty; namely, CRF peptide analogs that exhibit CRF agonist activities and bind to CRFR1 receptors with an affinity far greater than they bind to CRFR2 receptors.

In response to the Examiner's objections to the claims, clerical changes have been made to claims 1, 5 and 9 to change the matters to which the Examiner drew attention.

In response to the rejection of the claims based upon 35 U.S.C. § 112, second paragraph, the preamble of claim 1 has been changed so as to recite a 38-residue or 39-residue CRFR1 ligand peptide; this reflects the possibility of the addition of the amino acid residue tyrosine at the N-terminus an optional addition. The clerical error pointed out with respect to claim 9 has been corrected.

The rejection of various of the claims under 35 U.S.C. § 112, first paragraph, based upon the written description requirement, is respectfully traversed in view of the claim amendments. The Examiner's indication that the three molecules recited in claim 3 would be free of prior art is acknowledged.

By the amendments and the new claims submitted herewith, Applicants have directed the inventive subject matter of claims 1 to 13 to a generic group of cyclic peptides wherein there is a cyclizing bond between the side chains of the amino acid residues that are present in the positions corresponding to positions 31 and 34 of the

native CRF molecule. Original claims 4, 8 and 10 have been canceled; however, in their place new claims 11 and 12 are presented to specifically cover the six analogs disclosed in Examples 2, 5C, 4, 5, 5A and 6H, respectively. New independent claim 13 is also submitted; it is patterned after claim 1 but is limited to cyclic peptide analogs that are based more directly on the human/rat CRF peptide wherein the optional substitutions recited are those that are found in Examples 1 and 4 through 6I. Independent claim 14 is directed to the elected species in either linear or cyclic form, test data for which appear in the specification.

It is submitted that independent claims 1 and 13 accordingly contain subject matter that was adequately described in the specification as filed and thus comply with the written description requirement. In this respect, all of the potential optional substituents that are set forth can be found in the multitude of Examples that are provided in the application, or are known equivalents thereof, e.g. methionine and norleucine; therefore, adequate description is present. For example, R<sub>8</sub> in claim 1 can either be leucine (Example 1) or isoleucine (Example 3E). It is thus submitted that the Applicants indeed had possession of the invention as now recited in claims 1 and 13 at the time the application was filed.

In this respect, the Examiner's attention is respectfully directed to U.S. Patent No. 7,141,546 which issued on November 28, 2006, directed to CRFR2 selective ligands, which patent contains claims of similar scope wherein there is an acyl group at the N-terminus of the molecule having up to 15 carbon atoms. Although the experimental compounds were all made with acetyl at the N-terminus, it is well known in the CRF

analog peptide art that there is substantial latitude in the acyl group that can be used, as a result of the work that has been done in this field during the past 20+ years. Accordingly, it has been common to claim these peptide analogs as having a preferred acyl group of no more than 7 carbon atoms or as one having no more than 15 carbon atoms, on the basis of this general knowledge in the art. See, for example, U.S. Patents Nos. 6,326,463; 6,323,312; 6,214,797; 5,874,227; 5,844,074; and many others dating back to No. 4,489,163.

With respect to the dependent claims, claims 2, 5 and 7 are patterned more directly after the amino acid sequence of the analog synthesized in Example 1. Likewise, the residues specified in dependent claim 6 all appear in the molecule synthesized in Example 1.

For the reasons set forth above, reconsideration of the rejection of claim 1 and various of the dependent claims for failure to meet the written description requirement is respectfully requested in view of the amendments that have been made to claim 1 and allowance of claim 1 and the claims dependent thereupon are respectfully requested.

Independent claims 1 and 13 have been written to define cyclic CRF agonists that are highly selective to CRFR1. Independent claim 14 is written to cover the elected species; namely, a particular CRF agonist peptide, which may be linear or cyclic form. The test data set forth at the end of Example 1 on pages 17 and 18 of the specification show that both the linear and cyclic peptides of this amino acid sequence show high affinity to CRFR1 and very low affinity to CRFR2. Likewise, both are shown to be

effective CRF agonists, having biological potency superior to the laboratory standard at that time, although the cyclic peptide was more potent than the linear version.

It was earlier indicated that the elected species and various of the other species were free of prior art, and it is submitted that the invention as defined by claims 1, 13 and 14 is likewise free of prior art. Accordingly, it is believed that independent claims 1, 13, 14 and dependent claims 2, 3, 5-7, 9, 11 and 12 should be allowed. Favorable action at an early date is courteously solicited.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

Address all correspondence to:  
FITCH, EVEN, TABIN & FLANNERY  
120 So. LaSalle Street, Ste. 1600  
Chicago, IL 60603

Direct telephone inquiries to:  
James J. Schumann  
(858) 552-1311  
San Diego, California Office of  
FITCH, EVEN, TABIN & FLANNERY  
J:\73933\73933AMB.FINAL response to office action.doc

/James J. Schumann/  
James J. Schumann  
Attorney for Applicant(s)  
Reg. No. 20,856

Date: July 23, 2007